

Serial No. 10/690,687

Remarks

Rejections Under 35 U.S.C. § 102(a) and 102(e) Over Sherman (U.S. Patent No. 6,713,495), Vijayaraghavan et al. (U.S. Patent Application No. 2003/0212274), Kamiyama et al. (U.S. Patent Application No. 2003/0181247) and Gustavsson et al. (U.S. Patent No. 6,207,188)

Claims 1-15 have been rejected as anticipated by Sherman, Vijayaraghavan et al., Kamiyama et al., and Gustavsson et al.

The applicants have amended all independent claims to recite amorphous esomeprazole magnesium of certain chiral purity. Claims 1 and 9 have been amended to recite an amorphous esomeprazole salt, which has a chiral purity of at least 99.0%. Newly added independent claims 39-41 recite an amorphous esomeprazole magnesium salt, which has a chiral purity of at least 99.0%, of about 99.8% and of 99.8% respectively.

Sherman discloses a magnesium salt of omeprazole. In some portions of the Sherman disclosure, Sherman states that magnesium omeprazole can be prepared with crystallinity under 67%, or under 25%. Example 3 of Sherman states that powder was examined which had crystallinity of under 25%. There is no X-ray diffraction data presented in Sherman. Sherman does not disclose the chiral purity of the amorphous omeprazole magnesium. In fact, there is no mention of chiral purity by Sherman. Therefore, the Applicants submit that Sherman does not anticipate the amended claims.

Similarly, Vijayaraghavan et al. discloses salts of amorphous omeprazole magnesium salt. The Applicants respectfully submit that Vijayaraghavan et al. does not anticipate the amended claims.

Gustavsson et al. too do not discuss chiral purity of omeprazole salts. The Applicants respectfully submit that Vijayaraghavan et al. does not anticipate the amended claims.

In summary, the Applicants believe that the current amendments moot the 102(a) and/or (e) rejections over Sherman (U.S. Patent No. 6,713,495), Vijayaraghavan et al. (U.S. Patent Application No. 2003/0212274), Kamiyama et al. (U.S. Patent Application No. 2003/0181247) and Gustavsson et al. (U.S. Patent No. 6,207,188).

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Rejection Under 35 U.S.C. § 103(a) Over Sherman (U.S. Patent No. 6,713,495), Vijayaraghavan et al. (U.S. Patent Application No. 2003/0212274), Kamiyama et al. (U.S. Patent Application No. 2003/0181247) and Gustavsson et al. (U.S. Patent No. 6,207,188) in view of Bohlin et al. (U.S. Patent No. 6,162,816) and Broeckx et al. (U.S. Patent Application No. 2004/0209918)

Claims 1-15 have been rejected as obvious over Sherman, Vijayaraghavan et al., Kamiyama et al., and Gustavsson et al. in view of Bohlin et al. and Broeckx et al. Applicants respectfully traverse the rejection for the following reasons.

As discussed above in relation to the 35 U.S.C. § 102(a) and 102(e) rejections, none of the cited references Sherman, Vijayaraghavan et al., Kamiyama et al., or Gustavsson et al. disclose or allude to esomeprazole.

Bohlin et al. discloses crystalline forms of esomeprazole in the neutral, that is, not the salt, form. This material may also be referred to as esomeprazole base. The freebase form and the salt form of a chemical compound exhibit very different solid state characteristics. Bohlin does not disclose esomeprazole salts at all. The Applicants respectfully submit that the present amendments to the moot any 35 U.S.C. § 102(a) and 102(e) rejection over Bohlin et al.

Broeckx et al. discloses processes for preparing particular benzimidazole-type compounds, and does not disclose the particular preparation of esomeprazole. Thus, there is no disclosure of an amorphous esomeprazole salt.

The Examiner apparently seeks to formulate a prima facie case of obviousness involving Bohlin et al. or Broeckx et al. and each of the references Sherman, Vijayaraghavan et al., Kamiyama et al. and Gustavsson et al. The last four references lack any disclosure of esomeprazole, and Bohlin et al. provides a neutral, solid state form of esomeprazole. There is no apparent motivation to combine the disclosure of Bohlin et al. with any of the disclosures of Sherman, Vijayaraghavan et al., Kamiyama et al. or Gustavsson et al. to arrive at applicants' presently claimed amorphous salts of esomeprazole. The Examiner has not identified any such motivation, merely stating "Bohlin et al. and Broeckx et al. teach that omeprazole is a racemic mixture that consists of two single enantiomers.

Applicants respectfully submit that the claimed subject matter is not obvious in light of the cited references.

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Rejection Under 35 U.S.C. § 112

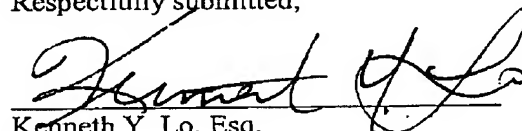
The amended claims, which recite chiral purity of amorphous esomeprazole magnesium, find support in Example 1. Applicants believe that the rejection based on 35 U.S.C. § 112, first and second paragraphs, have been overcome by the current amendments.

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Conclusion

Applicants submit that all outstanding rejections in the Office Action dated September 14, 2007 have been overcome or mooted, and a Notice of Allowance is respectfully requested at this time. Authorization is hereby given to charge any fees or credits due in connection with this Response to Office Action to Deposit Account No. 50-0912.

Respectfully submitted,



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